Scientific Opinion on the use of existing environmental surveillance networks to support the post-market environmental monitoring of genetically modified plants

Arpaia, Salvatore ; Birch, Andrew Nicholas Edmund ; Chesson, Andrew ; du Jardin, Patrick ; Gathmann, Achim ; Gropp, Jürgen ; Lieve, Herman ; Hoen-Sorteberg, Hilde-Gunn ; Jones, Huw ; Kiss, József ; Kleter, Gijs ; Løvik, Martinus ; Messéan, Antoine ; Naegeli, Hanspeter ; Nielsen, Kaare Magne ; Ovesná, Jaroslava ; Perry, Joe ; Rostoks, Nils

Abstract: Following a request from the European Commission, a set of assessment criteria was developed to support the selection of existing environmental surveillance networks for post-market environmental monitoring (PMEM) of genetically modified plants (GMPs). In compliance with these criteria, some networks and associated programmes were identified as being of potential use subject to further case-by-case analysis. When considering PMEM of GMPs, the approach would also require comparing sites monitored by the networks and the locations where GMPs are cultivated. The reporting of the sites surveyed by networks and locations of cultivated GMPs should thus follow the same standards in order to ensure interoperability and to potentially establish a causal link between a change observed and the GMPs. In this respect, technical support might be required by networks to transform their data records into workable standards. Moreover, the EFSA GMO Panel was asked by the European Commission to examine the sensitivity of statistical analyses used by the networks to detect change. A decision tree is provided for selecting the optimal method for statistical analysis based on the study design and the datasets from networks. Sufficient statistical power needs to be ensured to detect an effect for a particular indicator. Sample size is one of the main contributing factors in determining the power of any network to detect an effect of a product release into the environment. Increasing the sample size implies variable extra-costs depending on whether data are collected by volunteers or professionals. A more powerful statistical analysis can also be achieved by pooling datasets collected by different networks; this needs further investigation because of important covariates leading to differentiated responses. In general, PMEM would benefit from a move towards 'open data' policies for re-analysis or pooling data collected by different networks.

DOI: https://doi.org/10.2903/j.efsa.2014.3883

Gijs; Løvik, Martinus; Messéan, Antoine; Naegeli, Hanspeter; Nielsen, Kaare Magne; Ovesná, Jaroslava; Perry, Joe; Rostoks, Nils (2014). Scientific Opinion on the use of existing environmental surveillance networks to support the post-market environmental monitoring of genetically modified plants. EFSA Journal, 12(11):3883.
DOI: https://doi.org/10.2903/j.efsa.2014.3883

SCIENTIFIC OPINION

Scientific Opinion on the use of existing environmental surveillance networks to support the post-market environmental monitoring of genetically modified plants[1]

EFSA Panel on Genetically Modified Organisms (GMOs)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following a request from the European Commission, a set of assessment criteria was developed to support the selection of existing environmental surveillance networks for post-market environmental monitoring (PMEM) of genetically modified plants (GMPs). In compliance with these criteria, some networks and associated programmes were identified as being of potential use subject to further case-by-case analysis. When considering PMEM of GMPs, the approach would also require comparing sites monitored by the networks and the locations where GMPs are cultivated. The reporting of the sites surveyed by networks and locations of cultivated GMPs should thus follow the same standards in order to ensure interoperability and to potentially establish a causal link between a change observed and the GMPs. In this respect, technical support might be required by networks to transform their data records into workable standards. Moreover, the EFSA GMO Panel was asked by the European Commission to examine the sensitivity of statistical analyses used by the networks to detect change. A decision tree is provided for selecting the optimal method for statistical analysis based on the study design and the datasets from networks. Sufficient statistical power needs to be ensured to detect an effect for a particular indicator. Sample size is one of the main contributing factors in determining the power of any network to detect an effect of a product release into the environment. Increasing the sample size implies variable extra-costs depending on whether data are collected by volunteers or professionals. A more powerful statistical analysis can also be achieved by pooling datasets collected by different networks; this needs further investigation because of important covariates leading to differentiated responses. In general, PMEM would benefit from a move towards ‘open data’ policies for re-analysis or pooling data collected by different networks.

KEY WORDS

genetically modified plant, post-market environmental monitoring, general surveillance, protection goals, surveillance/monitoring networks

---

[1] On request from the European Commission, Question No EFSA-Q-2014-00583, adopted on 23 October 2014.

[2] Panel members: Salvatore Arpaia, Andrew Nicholas Edmund Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Lieve Herman, Hilde-Gunn Hoen-Sorteberg, Huw Jones, József Kiss, Gijs Kleter, Pagona Lagiou, Martinus Lovik, Antoine Messéan, Hanspeter Naegeli, Kaare Magne Nielsen, Jaroslava Ovesna, Joe Perry, Nils Rostoks and Christoph Tebbe. Correspondence: gmo@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the standing Working Groups on Environmental Risk Assessment and Annual PMEM reports for the preparatory work on this scientific opinion and EFSA staff: Jose Cortinas-Abrahantes and Jane Richardson for the valuable support provided to this scientific opinion.

Suggested citation: EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on the use of existing environmental surveillance networks to support the post-market environmental monitoring of genetically modified plants. EFSA Journal 2014;12(11):3883, 24 pp. doi:10.2903/j.efsa.2014.3883

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following a request from the European Commission, an inventory of more than 500 current environmental organisations and almost 1 000 existing surveillance networks/programmes (ESNs[4]) was established by an external contractor to provide an overview of existing networks and associated surveillance programmes at this point in time. The inventory is incomplete because all ESNs are not listed and because, for ESNs reported in the inventory, information was not available or not found during the survey (e.g. sampling protocols, statistical analysis methodologies and data validation). However, the inventory headings can serve as a checklist in the initial process of identifying potentially suitable ESNs prior to an in-depth analysis of their suitability for general surveillance (GS) of genetically modified plants (GMPs). It would therefore be desirable to complete, maintain and update this inventory as a resource for supporting GS.

The EFSA GMO Panel first defined the following assessment criteria to support the selection of ESNs suitable for post-market environmental monitoring (PMEM) of agricultural products (e.g. GMPs): the spatial resolution, the temporal resolution, a standard protocol for data collection, a survey carried out by professional surveyors and/or at least trained volunteers, data validation, the statistical analysis of collected data, and the availability and accessibility of collected data. When considering GS for GMPs, these criteria should be adapted on a case-by-case basis considering the geographical distribution of species/taxon relevant to the receiving environments for the GMP under consideration, the temporal resolution of an ESN depending on the biology (e.g. life cycle) and behaviour (e.g. migration) of the species/taxon relevant to the receiving environment covered by the ESNs and the type of data collection (‘continuous’ or ‘count’) in order to achieve good power to detect change. Moreover, the types of endpoints measured by the ESNs must be of relevance for GS; it is important that the selected biota occur in areas where GMPs may be cultivated.

The EFSA GMO Panel acknowledges that, in compliance with the aforementioned assessment criteria, several existing ESNs potentially suitable for GS of GMPs have been identified but considers that further analysis is needed to identify all the ESNs that could be used. In many cases, spatial resolution of ESNs does not cover agricultural landscapes where the GMPs may be cultivated. In addition, they only partly cover the protection goals identified by the EFSA GMO Panel in its 2011 Guidance Document on PMEM of GMPs in regions where GMPs might be cultivated. Further information on ESNs is still needed and direct contact with ESN organisers would be required to determine if the ESN fully meets requirements and to discuss options for access to data.

In this respect, raw data are only exceptionally available. Although problems currently exist in accessing data from ESNs, the move towards ‘open data’ policies may resolve these issues in the future. The EFSA GMO Panel is therefore of the opinion that GS of GMPs would benefit from open data policies applied by ESNs, as this would allow (re-)analysis and/or pooling of datasets collected by different ESNs, as well as the study of any interactions between datasets. Overall, the EFSA GMO Panel supports the centralisation and harmonisation of data recording according to European Union (EU) standards, such a those laid down in Directive 2007/2/EC[5] establishing an Infrastructure for Spatial Information in the European Community (INSPIRE). However, the EFSA GMO Panel also recognises that technical support may be required by certain ESNs in order to transform their collected datasets to meet INSPIRE standards.

In addition, in the context of GS of GMPs, the monitoring sites or regions must be characterised for their level of exposure to GMPs to identify if there is a plausible link between the potential adverse effect and the cultivated GMP. This would require comparing the spatial and temporal resolution of the monitoring sites or regions with known locations of GMP cultivation. However, monitoring sites are not limited to single fields and usually cover a small agricultural area. Moreover, the uptake of GMPs may vary over time. Therefore, they cannot always be classified as either non-exposed (‘control’) or exposed (‘treated’) and would instead be characterised by the level of uptake of GMPs, which makes data analysis more complex. In such cases, an alternative approach, based on historical data to establish baselines and monitoring sites over time, may be required. The GMO registers could be the source for information for GMP cultivation. However, the availability of information on influencing factors (e.g. cropping systems) would provide added value to account for confounding factors and assess to what extent any adverse effect is associated with the GMP or with any other stressors. Ideally, the reporting of the locations should be the same for both monitoring sites and cultivation sites in terms of scale, format and projection system. Recording and reporting locations according to the INSPIRE standard for both monitoring sites and GMO registers would ensure interoperability.

---

[4] An ESN is defined as an organisation contributing to one or more environmental surveillance programme(s).

[5] Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE). OJ L 108/1, 25.4.2007, p. 1–14.

The EFSA GMO Panel was also asked by the European Commission to further investigate data analyses by ESNs as well as on the sensitivity of these statistical analyses to detect change. The statistical method for data analysis is one of the assessment criteria listed herein for the selection of ESNs suitable for GS of GMPs. A decision tree is provided for selecting the optimal method for statistical analysis based on the study design, and the datasets available from ESNs in the case monitoring sites can be classified as either ‘exposed to GMPs’ or ‘non-exposed to GMPs’. A survey design with sufficient statistical power (> 70 %) is required to detect an effect for a particular indicator. A generic equation is also provided to estimate the power of a specific network to detect change considering such factors as number of sites, frequency of observations, missing data, data type and proportion of sites in areas of GM cultivation. This can be used during the case-by-case analysis to identify suitable ESNs.

For all data types, increasing the number or monitoring sites and/or the number of years of monitoring increases the power to detect an effect. Sample size is one of the main contributing factors in determining the power of any ESN to detect an effect of a product release into the environment. A different way to achieve a more powerful statistical analysis is to pool data collected by different ESNs covering the same protection goal(s). Although increasing the sample size of any ESN activity may have a positive effect on the power to detect any treatment effect, it also implies variable extra-costs depending on whether data collection is in the hands of volunteers or professionals. Moreover, combining results for different ESNs is not always appropriate, as there may be important covariates (e.g. receiving environments and/or stressors) leading to differentiated responses across geographical regions and different elements of variability from each constituent data supplier. Complex hierarchical models would be needed to fully investigate the advantages and disadvantages of combining data across ESNs. As this is an important issue to improve the efficiency of using ESNs for the purpose of GS, the EFSA GMO Panel recommends further investigation of the combination of datasets from different ESNs and conducting simulation exercises on selected case-studies.

Monitoring the environmental impacts of GMPs should be considered as a component of the environmental monitoring that is required to measure impacts of land use and management on biodiversity and the environment in the EU. In order to determine which human interventions are associated with environmental impacts, the EFSA GMO Panel recommends that all relevant environmental monitoring is fully integrated, so that data on all major agricultural and land use stressors (e.g. pesticides, cropping management practices) can be collated and analysed. Harmonisation and synchronisation of environmental monitoring would facilitate analysis and interpretation of monitoring reports and provide a strong scientific basis for supporting land use and environmental policy.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION AND THE EFSA

According to Directive 2001/18/EC[6] and Regulation (EC) No 1829/2003[7], the authorisation to cultivate a genetically modified (GM) crop requires the notifier to ensure that post-market environmental monitoring (PMEM) and reporting are carried out according to the conditions specified in the authorisation.

According to Annex VII of Directive 2001/18/EC, the objectives of a post-market monitoring plan are : (1) case-specific monitoring (CSM) to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GM plant (GMP) or its use in the Environmental Risk Assessment (ERA) are correct, and (2) general surveillance (GS) to identify the occurrence of adverse effects of the GMP or its use on human health or the environment which were not anticipated in the ERA. On the one hand, the hypothesis-driven CSM is not compulsory but may be included in a GMO application in order to confirm the outcomes of the ERA. On the other hand, GS, which is not hypothesis driven, is required in all cases for each GMO application even if no adverse effects have been identified in the ERA (EFSA, 2011). In practice, GS should identify the aspects of the environment that need to be protected from harm (environmental protection goals) due to the release and cultivation of the GMP and be designed to monitor impacts on assessment endpoints associated with these environmental protection goals (EFSA, 2011).

According to the EFSA Guidance Document on PMEM of GMPs (EFSA, 2011), a plan for GS has three main approaches: (1) monitoring of the GMP and its cultivation site(s) mainly through farmer questionnaires, (2) monitoring at larger scale by utilising the data collected by existing monitoring networks active in surveys at local/regional/national scale and (3) review of the scientific literature.

Whereas the legal obligation to carry out and report on PMEM is with the applicants, the EFSA GMO Panel already acknowledged the need for support from risk managers in establishing and implementing the PMEM plans (e.g. by involvement of existing networks) (EFSA, 2011). Since 2011, the European Commission and Member States have been discussing how procedures for GS of GMPs could be improved and, on the 29 March 2012, the European Commission held a public hearing[8] on the PMEM of GMOs. Since then the European Commission, Member States and EFSA have continued to engage in regular discussions which have focused on the potential use of existing networks by the Member States to complement the monitoring carried out by applicants.

These initiatives have confirmed that variable amounts of environmental and agronomic data are already collected in the framework of various European legislations and, where appropriate, could support the GS of GMPs.

Council Decision 2002/811/EC[9] establishing guidance notes supplementing Annex VII to Directive 2001/18/EC forsees the possibility for Member States to carry out additional monitoring that will enable risk managers to take appropriate measures without delay should any undesirable and unidentified effects arise. Furthermore, Council Decision 2002/811/EC also states that: "*Existing observation programmes to be adapted to the needs of monitoring GMOs as a means to ensure comparability and to limit the expenditure of resources in developing the approach*". It suggests that GS could, where compatible, make use of established routine surveillance practices including ecological monitoring and environmental observation and nature conservation programmes.

Consequently, on 22nd May 2012, the European Commission requested EFSA to compile an inventory of existing environmental surveillance networks at European and national level, and to develop a set of assessment criteria to help determine the suitability and quality of the data collected by such networks as regards their potential use to strengthen the GS of GMPs cultivated in the European Union (EU) already undertaken by applicants.

[6] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106/1, 17.4.2001, p. 1–38.

[7] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268/1, 18.10.2003, p. 1–23.

[8] http://ec.europa.eu/food/food/biotechnology/docs/agenda_29032012_en.pdf

[9] Council Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 280/27, 18.10.2002, p. 27–36.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION[10]

EFSA is requested to consider the potential for the use of existing environmental surveillance networks for PMEM.

EFSA is requested to develop a set of criteria than can be used to identify existing environmental monitoring networks and those under development that may be used for PMEM. The criteria should consider as a minimum the following:

(1) The coverage/scale of the networks (i.e. EU, national, and if applicable local),

(2) The data quality,

(3) The continuity of data collection,

(4) The species/taxon that are monitored and their potential to be used as indicators for PMEM,

(5) The suitability of data for statistical analysis.

Issues regarding data ownership and availability as well as recording and sharing data across borders should be assessed and investigated at both Member State and EU level and should include consideration of the ongoing work on IT infrastructure, data connectivity, or sharing of environmental data (e.g. INSPIRE Directive, Biodiversity Information System for EUROPE (BISE)).

For those networks that meet the minimum criteria, more detailed information and analyses should be provided including:

- The driver behind their establishment (e.g. established in response to EU legislation obligations, national acts, NGO interests) and, if specified, the associated protection goals;
- The GM crops for which they could be used for the purposes of PMEM;
- The sensitivity to detect change, e.g. time lags and influencing factors such as scale and aggregation of GM uptake (see e.g. RIVM, 2012; ACRE, 2012);
- The compatibility with other data sets (including GMO registers) for analysis of trends and accessibility of data;
- The implications of variations across networks e.g. sampling intervals, methodologies for collection, storage and analysis of data;
- The costs associated with the statistical analysis of data and potential costs associated with increasing a network sensitivity (e.g. by increasing sampling density) need to be fully understood.

Finally, if applicable, a review of new and proposed networks that are either in the pipeline or underway and may be considered suitable for the purposes of PMEM but for example do not yet have sufficient baseline data to be considered (e.g. bees) would aid future planning.

[10] See http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?unit=AMU (with Question Number EFSA-Q-2012-00721).

ASSESSMENT

The objective of general surveillance (GS) is to identify potential adverse effects on human health or the environment that could arise directly or indirectly from genetically modified plants (GMPs) that were not identified during the environmental risk assessment (ERA). According to the EFSA Guidance Document on post-market environmental monitoring (PMEM) of GMPs (EFSA, 2011), GS follows a stepwise approach in order to:

- detect a change (i.e. an alteration that results in values that fall outside the normal range, given the variation due to changes in management practices, receiving environments and associated biota in the European Union (EU));
- determine whether the change is causing an adverse effect (e.g. causing irreversible damage to a protection goal);
- determine whether the adverse effect is associated with the release or cultivation of the GMP.

Different tools are available to monitor for changes and associated potential unanticipated adverse effects: (1) farmer questionnaires compiling data/observations on the fields cultivated with GMPs and their close surroundings; (2) the use of existing agronomic and environmental surveillance networks established by land use and environmental organisations (e.g. Gathmann, 2008; Sanvido et al., 2008a, b); and (3) the review of the scientific literature.

In response to the present request of the European Commission, an external open call[11] for tender to 'review statistical methods and data requirements to support post-market environmental monitoring of agro-ecosystems' was launched by the EFSA Assessment and Methodological Support Unit (AMU) in June 2012. The main objective of the call was to investigate whether data obtained from existing surveillance networks and associated programmes[12] (hereafter referred to as 'ESNs') can effectively contribute to PMEM of new and existing agricultural products (e.g. genetically modified organisms (GMOs), pesticides) authorised for use in Europe.

In March 2014, the external contractor[13] delivered its final report (see Appendix A). The report includes: (1) a review of published statistical methods used in the analysis of ecological and environmental datasets; (2) an inventory of statistical approaches in ecological and environmental monitoring and identification of data requirements for the items in the inventory; (3) an inventory of European, National and Regional ESNs and ESPs; and (4) recommendations of the most appropriate analysis methodologies for PMEM of agro-ecosystems.

In preparing this scientific opinion, the EFSA GMO Panel considered the report by the external contractor, the expertise of the two standing working groups[14] of the EFSA GMO Panel on the ERA and on annual PMEM reports, various sources of information such as scientific literature and expert consultation. Details on the methodology used by the contractor are not reported here but can be found in the final report (see Appendix A).

The present opinion complements the EFSA Guidance Document on PMEM of GMPs (EFSA, 2011). It provides risk managers and applicants with more detailed guidance, including criteria against which existing ESNs might be assessed for data quality and suitability for GS of GMPs cultivated in the EU.

1. Introduction

In order to address all the questions from the European Commission (see Terms of Reference), this opinion is structured as follows:

- Inventory of ESNs at EU, national and, if applicable, local scale.
- Assessment criteria for ESNs suitability for PMEM of GMPs:
  - concerns pertaining to data ownership and availability;

---

[11] Text of publication in the Official Journal of the European Union: http://ted.europa.eu/udl?uri=TED:NOTICE:190839-2012:TEXT:EN:HTML

[12] An ESN is defined as an organisation contributing to one or more environmental surveillance programme(s).

[13] Consortium composed of Centre for Ecology and Hydrology, Perseus, Rijksinstituut voor Volksgezondheid en Milieu.

[14] http://www.efsa.europa.eu/en/gmo/gmowgs.htm

  - concerns related to data connectivity and sharing of environmental data.
- Description of ESNs appropriate for PMEM of GMPs, accounting for:
  - the driver(s) and, if specified, protection goal(s) behind their establishment;
  - the GMPs for which ESNs could be used for PMEM;
  - the ESNs sensitivity to detect change;
  - the implications of variation across networks;
  - the compatibility with other datasets (including GMO registers) for analysis of trends and accessibility of data;
  - the costs associated with increasing ESN sensitivity.
- New surveys and future planning.
- Conclusions and recommendations on the use of ESNs for PMEM of GMPs.

2. Inventory of ESNs at EU, national and, if applicable, local scale

Based on existing database, literature and website searches, and a survey of EU Member States, more than 500 environmental organisations and almost 1 000 existing surveillance networks/programmes (ESNs[15]) have been identified and described in an overall inventory (see Appendix B).

The inventory supports filtering and sorting and provides the following information:

- objectives of the programme including protection goal(s), whether the programme was established to meet legal requirements (e.g. academic/environmental/governmental organisations), and sources of funding;
- monitoring methodology used including selection of sampling sites, use of protocols, types of observations recorded and status of the surveyors (e.g. trained professionals or volunteers);
- geographical and temporal coverage and resolution;
- availability of the reports, including data and types of analysis used in these reports.

For further details on the inventory, please consult Tables 9 and 10 in Section 3.2 of Appendix A. Owing to the inventory being based on publicly available information (e.g. websites and published reports for the ESNs), there are several ESNs that are not reported and there are information[16] gaps, in particular in the areas of sampling protocols, statistical analysis methodologies and data validation.

Based on the diversity of their organisational aspects, the ESNs can be divided into four categories: (1) governmental networks at national or European level established by EU legislation; (2) academic networks focusing on scientific research; (3) nature conservation networks involved in education or the promotion and observation of nature; and (4) professional networks made of interest groups (e.g. farmers, beekeepers (see also Smets et al., 2014)).

The EFSA GMO Panel acknowledges that these four types of ESNs focus on different aspects of the environment and collect information on a range of endpoints covering the protection goals relevant to agro-ecosystems where crops, including GMPs, may be cultivated (e.g. conservation of fauna and flora, sustainability of agro-ecosystems, as listed in EFSA (2011)). However, the existing inventory is incomplete, and so it would be desirable to complete, maintain and update it as a resource for supporting GS. Moreover, the inventory headings can serve as a checklist in the initial process of identifying potentially suitable ESNs prior to an in-depth analysis of their suitability for GS of GMPs.

3. Assessment criteria for ESNs suitability for PMEM of GMPs

In its 2011 Guidance Document on PMEM of GMPs (EFSA, 2011), the EFSA GMO Panel acknowledged the utility of data and observations collected by ESNs as well as their limitations for GS of GMPs (e.g. data

[15] An ESN is defined as an organisation contributing to one or more environmental surveillance programme(s).
[16] i.e. because it was not available or because it was not found during the survey.

accuracy and quality are not always ensured when the survey uses surveyors with insufficient training, the sampling frequency and distribution do not always follow a defined protocol, and raw data are not accessible).

Additional points are raised in Appendix A (e.g. complex interrelationship between networks involved in the same surveillance programme, data portals with limited information on contributing programmes publishing only low-resolution data) that might impede or limit the use of ESNs for GS of GMPs. Overall, ESNs have been designed for other purposes and may not have appropriate spatial and temporal coverage or include suitable endpoints (EFSA, 2011).

However, considering the statistical requirements for an appropriate survey design to detect environmental changes, the external contractor defined the following assessment criteria[17] to assist in the selection of suitable ESNs to detect environmental changes (see Section 3.4.1.2 of Appendix A):

- The spatial resolution is:
  - at the European scale (i.e. a broad geographical area);
  - multisite with an even distribution (i.e. with a dense and even distribution of collection points).
- The temporal resolution is at least one year (visited regularly, for example once each year).
- A standard protocol for data collection is described (i.e. documentation of data collection) and applied.
- The survey is carried out by professional surveyors and/or at least trained volunteers who follow clearly defined and documented data collection methods.
- Validation of the data collected is essential.
- The method for data analysis (e.g. univariate or multivariate) is well documented.
- The data collected (i.e. summaries with graphs and figures) are made available; access to raw data either upon request or publicly available is ideal.

While acknowledging the relevance of the above criteria, the EFSA GMO Panel considers that some flexibility is needed when considering GS for GMPs and that they should be adapted on a case-by-case basis:

- Depending on the geographical distribution of species/taxon relevant to the crop under consideration as well as the possible receiving environments for the GM crop, spatial resolution of an ESN might not only be EU wide but could also cover local or national scales. Ideally, data collection points occur across agricultural landscapes where GM crops may be cultivated.
- Temporal resolution of an ESN might differ from the above referred annual basis, mainly depending on the biology (e.g. life cycle) and behaviour (e.g. migration) of the species/taxon relevant to GS of GM crops to be surveyed. ESNs should be recording with consistent frequency and preferably have already accumulated several years of data.
- For data collection, preference should be given to ‘continuous’ or ‘count’ data-type records in order to achieve good power to detect change. Lang and Bühler (2012) recommend recording mean species numbers as a method to increase survey power without increasing the number of survey sites in their analysis of survey optimisation for butterfly monitoring.

The assessment criteria should also consider the types of endpoints measured. It is important that the endpoints are direct or indirect measurement endpoints that can be linked to environmental protection goals[18]. Where the endpoints are counts of individual or groups of species, it is important that the species selected occur in areas where GMOs may be cultivated. Ideally, these species will be integral parts of the agro-ecosystem and therefore be sensitive indicators for environmental change.

The EFSA GMO Panel recommends applicants and risk managers to consider these assessment criteria in selecting ESNs suitable for GS of GMPs (see also Section 4).

[17] See also Table 14 in Section 3.4.2 of Appendix A.

[18] For further information on the ongoing EFSA Working Group dealing with the operationalisation of protection goals, please consult: http://www.efsa.europa.eu/en/scerwgs/documents/era_overarching.pdf

3.1. Concerns pertaining to data ownership and availability

Overall summary reports with graphs, communications, distribution maps and other publications are made publicly available (Smets et al., 2014). While they represent a contextual interpretation, they may not allow subsequent analysis and/or interpretation with other datasets owing to, for example, different methodology or different parameters. Availability of raw data is therefore considered very important, as it allows users to perform statistical analysis or other forms of additional evaluation and, where appropriate, to pool datasets from the same or different ESNs to increase the sensitivity of the method to detect a change (see Section 4.3). Raw data also provide details on sampling frequency and distribution (i.e. time and location).

In general, raw data are only exceptionally available, predominantly in the UK (e.g. Environmental Change Network (ECN) Data Centre[19]), the Netherlands (Natuurloket[20]) and Sweden (ArtPortalen (ESP13-0002[21])). In some cases, access to information/data is granted under strict conditions of use or restricted to members only (see Section 3.4.1.2 of Appendix A).

There is a move within the scientific community towards ‘open data’ policies. The European Commission communication[22] (2012) states that ‘open access policies will be implemented under “Horizon 2020” ’ and that ‘to improve access to scientific information, Member States, research funding bodies, researchers, scientific publishers, universities and their libraries, innovative industries, and society at large need to work together. Europe’s scientific information system must be made fit for the digital age so that the “fifth freedom” of the EU — the free circulation of knowledge — can become a reality.’

This is further supported by the Royal Society of Science in its 2012 report[23] entitled ‘Science as an open enterprise’ stating that ‘It is vital to share data in a way that balances the rights and responsibilities of those who generate and those who use data, and which recognises the contributions and expectations of the individuals and communities who have participated in the research. The report delivers various recommendations, all striving to open up scientific data to the scientific community, as well as to the broader public, and to share data, information and knowledge in a joint effort by industry sectors and relevant regulators.

Although problems currently exist in accessing data from ESNs, the move towards ‘open data’ policies may resolve these issues in the future. The EFSA GMO Panel is therefore of the opinion that GS of GMPs would benefit from open data policies applied by ESNs in a broader environmental monitoring context.

3.2. Concerns related to data connectivity and sharing of environmental data

ESNs, and their associated existing surveillance programmes, were identified at national and EU level, which covered a broad range of protection goals (see Table 12 in Section 3.4.1 of Appendix A). A smaller number of ESNs were identified which addressed influencing factors (e.g. agronomic practices, GMO cultivation, land use and management) in their monitoring programmes (see Table 13 in Section 3.4.1 of Appendix A).

Biodiversity monitoring would benefit from observations on a wide range of biota that are often covered by different ESNs. In addition, any changes should consider influencing factors (e.g. uptake of GM crops and management systems) occurring in the region of interest that could have affected the specific endpoints under consideration.

As a consequence, mechanisms to combine data from different ESNs will be required. Agreed data standards and controlled terminologies allow scientists to share and exchange data from different monitoring and research programmes. For environmental monitoring the agreement of controlled terminology for species identification is particularly important. In the area of biodiversity research, the requirements to share information on the presence of new, rare or endangered species to ensure the success of conservation programmes has driven the development of data standards.

[19] data.ecn.ac.uk/access.asp
[20] www.natuurloket.nl/natuurloket
[21] See Appendix B.
[22] http://ec.europa.eu/research/science-society/document_library/pdf_06/era-communication-towards-better-access-to-scientific-information_en.pdf
[23] https://royalsociety.org/~/media/Royal_Society_Content/policy/projects/sape/2012-06-20-SAOE.pdf

The Global Biodiversity Information Facility (GBIF)[24] is an international open data infrastructure that allows researchers to upload or download data on the geographical occurrence of species. In order to achieve this, Darwin Core[25] was developed, which provides a set of defined terms for reporting the results of species monitoring/sightings. Only two ESNs, the Joint Nature Conservation Committee (UK) and the National Biodiversity Data Centre (Ireland) from the inventory (see Appendix B) were recorded as using the GBIF data standard.

Infrastructure for Spatial Information in the European Community (INSPIRE) is a framework adopted in European Directive 2007/2/EC[26] in order to facilitate the usage and sharing of spatial data to support environmental policies. According to that Directive, Member States have to transpose this framework into their governmental infrastructures. The adopted metadata standard addresses 34 spatial data themes split between three annexes. Annex I includes protected sites and supports reporting of spatial data for Natura 2000 and the Habitats Directive[27]. Annex III includes soil, land use, agricultural facilities and species distribution. For reporting species distribution the controlled terminology EU-Nomen[28] (an all-taxa inventory of European species) is recommended. The Darwin Core terms are used within the XML standard for the species distribution data theme.

In the inventory (see Section 2 and Appendix B), five Slovakian ESNs are recorded as using the INSPIRE data standard for the reporting of both water quality monitoring and biodiversity monitoring. This information is aggregated at the Enviroportal (see 'ESP13-0192' in Appendix B). Two ESNs in France and three in the UK were also recorded as complying with the INSPIRE data standard.

The preparation and transformation of datasets into formats compliant with INSPIRE standards could imply additional workload and could be complex when original data structures and terminologies are quite distinct from these standards. As a consequence, technical support for the ESNs may be required in order to achieve compliance. This support would be especially valuable for smaller ESNs with limited access to information technology technicians. It should be noted that privately funded organisations would not be required to comply with INSPIRE data standards.

The inventory also includes a number of data portals; these host data are often collated from smaller regional ESNs with shared objectives. In these cases, the portals themselves may not be actively involved in surveying and monitoring and, as a consequence, detailed information on the monitoring methodologies may not be available. Examples of data portals at European and national level are:

- European Soil Data Centre (see 'ESP13-0138' in the inventory) hosts European data on soil profiles and properties (e.g. organic carbon, pH, total nitrogen).
- The Biodiversity Information System for Europe (BISE) (see 'ESP13-0267' in Appendix B) hosts information on the location of protected sites and status of Red List species reported under the Birds Directive[29] and Habitats Directive[30].

[24] www.gbif.org/
[25] http://rs.tdwg.org/dwc/terms/
[26] Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE). OJ L 108/1, 25.4.2007, p. 1–14.
[27] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora. OJ L 206/7, 22.7.1992, p. 7–50.
[28] http://www.eu-nomen.eu/portal/
[29] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds. OJ L 20/7, 26.1.2010, p. 7–25.
[30] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora. OJ L 206/7, 22.7.1992, p. 7–50.

- The Water Information System for Europe (see 'ESP13-0266' in Appendix B) hosts water quality data for inland, coastal and marine waters reported under the Water Framework Directive[31] and Directive 2008/105/EC[32].
- AirBase (see 'ESP13-0227' in Appendix B) hosts air quality data reported under Council Decision 97/101/EC[33], Directive 96/62/EC[34] on Air Quality and Commission Decision 2001/752/EC[35].
- National Biodiversity Network (see 'ESP13-0128' in Appendix B) in the UK acts as a 'Data warehouse' for biodiversity information.
- Nationale Databank Flora en Fauna (see 'ESN13-0268' in Appendix B) in the Netherlands.

The existence of these data portals at both national and European level indicates that progress is being made towards the recommendations made by the EFSA GMO Panel in its 2011 Guidance Document on PMEM of GMPs (EFSA, 2011). The EFSA GMO Panel already stressed the need to centralise the recording of data collected by ESNs at national and, where appropriate, European level. Recommendations to Member States are to establish reporting centres for PMEM data aiming at, for example:

- compiling the reports from all ESNs supplying data from areas where GMPs are cultivated or released with access to raw data, if required;
- combining the information of the cultivation registers, referred to in Article 31(3)(b) of Directive 2001/18/EC (EC, 2001), with location references which can be correlated with GPS references and field references within each Member State (see Section 4.5).

The reporting centres should agree to share information and data with other reporting centres in other countries so that they can conduct analyses across wider regions (see case-study 2 in Section 3.4.1.2 of Appendix A).

There is clearly a move towards 'open data' policies and use of data standards to allow datasets generated by diverse monitoring programmes at local, national and European level to be combined and shared via data portals, supporting both environmental monitoring and environmental policies (see also Section 3.1). However, these data also need to be 'fit for purpose'; therefore, the EFSA GMO Panel advises that caution should be applied when using data obtained from a study design with a specific objective for purposes beyond the original study design.

Overall, the EFSA GMO Panel supports the centralisation and harmonisation of data recording according to EU standards, such a those laid down in the INSPIRE Directive. However, the EFSA GMO Panel also recognises that technical support may be required by certain ESNs in order to transform their collected datasets to meet INSPIRE standards.

4. Description of ESNs appropriate for PMEM of GMPs

In Section 3, assessment criteria are provided to applicants and risk managers to support their initial selection of ESNs suitable for GS of GMPs.

From the inventory (see Appendix B), the external contractor identified[36] ESNs suitable for PMEM of agro-ecosystems and in compliance with the assessment criteria listed in Section 3. However, further information

[31] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. OJ L 327/1, 22.12.2000, p. 1–73.

[32] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council. OJ L 348/84, 24.12.2008, p. 84–97.

[33] Council Decision 97/101/EC of 27 January 1997 establishing a reciprocal exchange of information and data from networks and individual stations measuring ambient air pollution within the Member States. OJ L 35/14, 5.2.1997, p.14–22.

[34] Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management. OJ L 296/55, 21.11.1996, p.55–63.

[35] Commission Decision 2001/752/EC of 17 October 2001 amending the Annexes to Council Decision 97/101/EC establishing a reciprocal exchange of information and data from networks and individual stations measuring ambient air pollution within the Member States (Text with EEA relevance) (notified under document number C(2001) 3093). OJ L 282/69, 26.10.2001, 69–76.

would be required to fully characterise a network and this should be obtained on a case-by-case basis. Contact with network organisers would be required to determine if the network fully meets requirements and to discuss options for access to data. Listed below are examples in which a more detailed examination of networks was applied.

The external contractor identified the Butterfly Monitoring Scheme as highly likely to serve for PMEM of agro-ecosystems. This is an example of a broader scale umbrella organisation providing an excellent foundation for pulling together information across networks and working to achieve consistency. These broad-scale initiatives were identified as suitable to support GS and highlight the importance of EU-wide programmes that bring together information that would be crucial for GS (for further details, see Section 4.3 of Appendix A and Table 1). Within the inventory are a number of national level programmes which contribute to this European initiative (e.g. Landelijk meetnet vlinders (ESP13-0050), Tagfalter-Monitoring Deutschland (ESP13-0056), Research Institute for Nature and Forest (INBO) - Dagvlinders (ESP13-0196), Standard-Transekt Monitoring (ESP13-0521)). This scheme is characterised by multiple site locations, observations made at least once per year, data collected according to some well-defined protocol by trained surveyors, information on whether data are validated and accessible and well-documented information on data collection methods and data analysis. It is noted that this scheme does not meet the requirement for even distribution of sites; this is because in some countries volunteers can select their own monitoring sites. However, since a large number of sites are surveyed across a broad range of different habitats and standardised protocols[37] are used, the results are considered to be representative of the European butterfly population (see also Lang and Bühler, 2012). Using data from this network, a European Grassland Butterfly Indicator has been calculated in order to investigate the effects of changes in agricultural practices and land use on butterfly populations (EEA, 2013). Two similar umbrella organisations exist for bird monitoring; Pan-European Common Bird Monitoring Scheme (ESP13-0110) and Constant Effort Sites Ringing (ESP13-0250).

Table 1: European Network Butterfly Conservation Europe

Network	**ESN13-0115: Butterfly Conservation Europe**
Objectives	Act as an umbrella organisation coordinating and stimulating recording and monitoring programmes. Aims to conserve butterflies, moths and their habitats across Europe
Spatial coverage	European—19 countries
Landscape coverage	Protected, agricultural and other landscape types
Multisite, even distribution	Multisite, uneven distribution, > 3 000 transects per year
Observations frequency	Annually from 1990 to present
Data type	Count
Endpoints	17 Grassland butterfly species
Protection goals	Biodiversity
Influencing factors	None
Standard protocol	Line transect method; between March–April to September–October, in good weather conditions; visual counting 5 m ahead and above, and 2.5 m on either side; on average 20 visits/year depending on country http://www.bc-europe.eu/upload/Manual_Butterfly_Monitoring.pdf
Trained surveyors	Trained professionals and trained volunteers
Validated data	Yes
Analysis method well documented	National population trends from the BMS[38] calculated by the programme TRIM[39] (Pannekoek and Van Strien, 2005), are combined to form supranational species trends
Access to raw data	As a summary report: http://www.bc-europe.eu/index.php?id=325; and http://www.eea.europa.eu/publications/the-european-grassland-butterfly-indicator-19902011

[36] Examples: Pan-European Common Bird Monitoring Scheme (see 'ESP13-0110' in the inventory), Constant Effort Sites Ringing (see 'ESP13-0250' in the inventory) and Butterfly Monitoring Scheme (see 'ESP13-0112' in the inventory).
[37] For example: http://www.ukbms.org/Methods.aspx, http://www.tagfalter-monitoring.de/
[38] Butterfly Monitoring Schemes (BMS)
[39] The TRends and Indices for Monitoring data (TRIM)

In the Netherlands, a number of ESNs were assessed on a case-by-case basis to investigate which networks could be used for the GS of GMPs (RIVM, 2012). The report identified the Ecological Monitoring Network (see Table 2) that follows the development of flora and fauna in the Netherlands, and the Biological Indicator System of Soil Quality that keeps track of soil quality. As with Butterfly Conservation Europe, sampling sites are unevenly distributed and, in addition, standardised protocols are not available for all endpoints. However, two test-cases demonstrated that resulting data could be used to detect changes in trends for species or species groups and be suitable for the purposes of GS.

Table 2: Netherlands Ecological Monitoring Network

Network	**ESN13-0051: Stichting Veld Onderzoek Flora en Fauna Ecological Monitoring Network**
Objectives	Aim is to monitor the development of Dutch flora and fauna within the scope of international nature policy frameworks, like the Birds and Habitats Directive
Spatial coverage	National—Netherlands
Landscape coverage	Protected, agricultural and other landscape types
Multisite, even distribution	Multisite, uneven distribution
Observation frequency	Monitoring of most species groups takes place on an annual basis and suitable monitored endpoints are included
Data type	Count
Endpoints	Data collected include: numbers of organisms of Dutch flora and fauna, general state of flora, farmland birds, birds of prey occurring in agricultural fields (owls), diurnal mammals (hare, roe deer), butterflies, Red List species
Protection goals	Biodiversity
Influencing factors	None
Standard protocol	Not reported
Trained surveyors	Measurements conducted by trained and organised volunteers (PGOs, i.e. particuliere gegevens-beherende organisaties) and by provincial networks
Validated data	Yes
Analysis method well documented	Data on species abundance are statistically analysed by Statistics Netherlands using log-linear regression with TRIM, software specially developed for the NEM[40] (van Strien et al., 2001)
Access to raw data	Data are stored in the National Flora and Fauna Database (NDFF) http://www.compendiumvoordeleefomgeving.nl/

The EFSA GMO Panel acknowledges that several existing ESNs potentially suitable for GS of GMPs have been identified but considers that further analysis is needed to identify all the ESNs that could be used. In many cases, spatial resolution of ESNs does not cover agricultural landscapes where the GM crops may be cultivated (Römbke et al., 2014; and http://www.man-gmp-ita.sinanet.isprambiente.it/documenti/output-finali/reti-di-monitoraggio-agro-ambientale/reti-di-monitoraggio-agro-ambientale). Further information on ESNs is still needed and direct contact with ESN organisers would be required to determine if the ESN fully meets requirements and to discuss options for access to data.

4.1. The driver(s) and, if specified, protection goal(s)[41] behind their establishment

The inventory of ESNs shows that there are existing monitoring schemes collecting data across a wide range of indicators that would be of potential use in GS. Globally, the inventory contains ESNs covering the protection goals such as air quality, animal health, biodiversity, human health, plant health, soil function, sustainable agriculture and water quality (see Table 12 in Appendix A). It is acknowledged that there are gaps and missing ESNs in the inventory. However, for some protection goals (e.g. biodiversity of birds and insects), there are ESNs in most Member States, and in many cases multiple ESNs within countries monitoring these organisms. On the contrary, for protection goals such as soil function/biodiversity fungi, only a small number of ESNs were identified. Generally, there is a focus in biodiversity monitoring towards larger species which can be observed and identified in the field without the requirement for sampling and laboratory testing.

[40] Network Ecological Monitoring (NEM)

[41] i.e. aspects of the environment that need to be protected from harm.

In many cases, the drivers behind the ESNs and associated programmes are European environmental monitoring legislation (i.e. Birds Directive, Habitats Directive, Natura 2000, Water Framework Directive) and the Berne Convention on the Conservation of European Wildlife and Natural Habitats. Other drivers for ESNs with biodiversity protection goals included indicators to measure, for example the success of land stewardship policies and sustainability projects, environmental/climatic change, exotic/invasive species and scientific research. In the human health domain, the ESPs in the inventory were largely related to monitoring of pollution and environmental contaminants.

In conclusion, existing ESNs suitable for GS of GMPs only partly cover the protection goals identified by the EFSA GMO Panel in its 2011 Guidance Document on PMEM of GMPs (EFSA, 2011) in regions where GMPs might be cultivated. The EFSA GMO Panel refers to ongoing activities[42] on the operationalisation of protection goals, which might help risk managers and Member States to specify relevant assessment endpoints.

4.2. The GMPs for which ESNs could be used for PMEM

In order to support the monitoring of possible unanticipated adverse effects of GMPs, Directive 2001/18/EC invites applicants and risk managers to use existing environmental surveillance tools such as ESNs. The ESNs were established to monitor specific aspects of the environment that need to be protected from harm in the frame of a holistic post-market monitoring approach, regardless of any stressor (e.g. GMP, pesticides). Therefore, the ESNs are considered to be applicable to all GMPs.

4.3. The ESNs' sensitivity to detect change(s)

4.3.1. Overall approach of GS of GMPs

As described in EFSA (2011), the major challenges in designing GS plans are:

- to detect a change (i.e. an alteration that results in values that fall outside the normal range, given the variation due to changes in management practices, receiving environments and associated biota in the EU);
- to determine whether the change is causing an adverse effect (e.g. causing irreversible damage to a protection goal); and
- to determine whether the adverse effect is associated with the release or cultivation of the GMP.

The design of the GS plan, and in particular the techniques to be used for exploratory and statistical analysis of data, will influence the quality and usefulness of resulting data. Hence, efforts should be made to ensure that data from monitoring can be statistically analysed (Wilhelm et al., 2003, 2004a, b, 2009; Graef et al., 2008 (in EFSA, 2011)). A scientific methodology shall be applied, wherever possible, in order to collect empirical data and establish certain baselines. This especially refers to defining sample sizes, sampling and recording methods, in order to produce valid data for inferences to detect any changes (EFSA, 2011). However, GS methodology and, in particular, the statistical method used by an ESN may not be adequate to detect an ecological or environmental change.

4.3.2. Inventory and evaluation of statistical methods for GS

First, the external contractor used literature searches and a consultation with statisticians to identify statistical methods routinely used or newer methods suitable for the analysis of environmental monitoring data. The standard approaches to detect environmental change are extensions of the Generalised Linear Model (GLM) concept, with model fitting using either a classic or a Bayesian framework. Non-parametric methods were proposed for a small sample size or distributional assumptions were clearly violated. Finally, certain niche methods, for example spectral analysis, were identified for approaches less commonly used but that could serve as useful tools.

This resulted in the list of statistical methods and the key publication describing each method (see Table 4 in Appendix A). For each of the statistical methods, examples of application to data from biodiversity monitoring datasets were listed, including an indication of data types, number of sites, frequency of observations and number variables used in the studies (see Table 6 in Appendix A).

[42] For further information on the ongoing EFSA Working Group dealing with the operationalisation of protection goals, please consult: http://www.efsa.europa.eu/en/scerwgs/documents/era_overarching.pdf

Second, a simulation study was carried out to assess the relative power of each statistical method to detect a hypothetical change (for further details, see Section 2 of Appendix A). The simulation study tested the null hypothesis, that there was no change in a given indicator over time, against the alternative hypothesis, that there was a linear trend over time. The three main data types recorded in ecological surveys (i.e. 'count' data, 'presence/absence' data and 'continuous' data) were simulated. Different values for the number of sites, start value, length of monitoring, samples per year, % change per year and number of variables (e.g. species recorded) were used in the simulations. The range of values for these simulation parameters were chosen to be representative of ESNs. The resulting simulated datasets were analysed using the methods listed in Table 8 in Appendix A. The key conclusions from the simulation studies considering the relative power of each statistical method to detect a hypothetical change were:

- No method was optimal for all data types.
- Generally, the non-parametric tests (Bootstrap resampling, Wilcox and Kruskal–Wallis) performed poorly compared with the parametric approaches, except when the sample size was small. If the sample size is reasonable, then the appropriate parametric approaches offer far greater power to detect change than non-parametric resampling or rank-based tests.
- Including random effects and autoregressive terms in a model can help tease out a signal in data that could be masked by site-to-site differences or heavy serial dependence in the observations. However, it is necessary to first test for random and autoregressive effects for each dataset before deciding which modelling approach to adopt.
- Generalised Estimating Equations (GEE) performed well when the sample size was sufficient.
- Where monitoring data include multiple species/variables, a multivariate analysis can be more powerful if common trends in populations among the species are expected. If there was an effect across multiple variables, as one may expect/hypothesise for post-authorisation of a regulated product (e.g. GMO) if many species were affected in a similar way, then a multivariate redundancy analysis could prove to be the most powerful.

Based on the results of the simulation study, a decision tree (see Figure 1 in Appendix A) was developed as a guideline for selecting the optimal method for statistical analysis based on the study design and the datasets available from ESNs. It is important that when analysing each dataset, care is given to the methods employed.

4.3.3. Sensitivity to detect change(s)

The statistical properties that determine the suitability of an ESN, and data they collect, for PMEM can be defined as the power that the network has to detect a potential change in the ecosystem. In Section 4 of Appendix A, the results of a large-scale simulation study are presented and discussed. The aim was to develop a model ('generic equation') which could predict the power of an ESN from a function of the key properties of that network (e.g. number of sites, proportion of treated sites). The simulation datasets covered a wide range of scenarios that describe and characterise various potential networks, the data they collect and the environmental indicators monitored. A total of nine predictor variables were considered: the slope, the number of sites visited, the proportion of sites treated, the abundance mean/site, the abundance variance between sites, the proportion of survey visits missed, the duration of the survey, the scale and the magnitude of the difference between the two treatments (for further details, see Table 15 in Appendix A). The simulation study tested the null hypothesis, that there is no difference in trends over time of two levels of a factor, against the alternative, that there is a difference. The two levels of a factor are referred to, subsequently, as treatment and control. A true control would not exist for most ESNs as there is just country-wide surveillance; therefore, the term control refers to all the areas and observations that are essentially not in the treatment category (e.g. areas of GMP cultivation).

The results indicate that for count data (Poisson model) a power to detect change of reasonable magnitude is achievable from a study of realistic dimensions. However, for presence/absence observations (binomial model) power is much reduced and substantial numbers of sites were required to achieve more than modest power (> 50 %) (see Figures 6–10 in Appendix A). This implies that when selecting suitable ESNs, if an ESN has the ability to capture information on abundance, cover or value rather than simply whether or not something was present, then, for the same number of sites monitored over the same time period, far greater power exists to detect the effect of a specific treatment.

For count data, the slope of the control sites had very little effect on power, which showed that, even if there was a strong background relationship over time, an additional effect could still be adequately captured. For scenarios where data observations were scarcer (≤ 150 sites), where the number of missing values was high (> 30 %), the power decreased considerably (Figure 7 in Appendix A). This suggests that when selecting an ESN with few sites, care should be taken to ensure that as few observations are missed as possible.

In the normal model, the variance was adopted as an extra predictor in the generic equation (observation error). The relationship between observation error and the average value of the observations was critical in determining power. When this error was large with respect to the initial mean abundance, for example, power was low (< 20 %), although with an enlarged study with a greater number of sites, the power decline is less steep (see Figures 12 and 13 in Appendix A). Therefore, a suitable ESN should do all it can to ensure that observation error is kept to an absolute minimum, perhaps by quality control procedures or training of surveyors.

For all data types, increasing the number of monitoring sites and/or the number of years of monitoring increases the power to detect an effect. Sample size is one of the main contributing factors that influences the estimated power of any network to detect an effect of a product release into the environment.

As the proportion of sites treated rose to the optimal value of 0.5 (which represents equal data in each of the treatment and control categories, a balanced design), the power significantly increased. As the hypothesis for the simulation concerns comparing a treatment effect (some change in the agro-ecosystem) versus a control effect (the response of the remaining population), it is important not just to have an overall sufficient sample size, but also sufficient sample size in each of the two (treatment/control) groups.

The criteria defined in Section 3 are based on the results of the simulation study.

4.4. Implications of variation across networks

A different way to achieve a more powerful statistical analysis is to pool data collected by different ESNs covering the same protection goal(s).

There are some clear examples of ESNs in the inventory (see Section 2) that collect the same information on the same environmental indicators but across different geographical regions (e.g. bird and butterfly monitoring). Each of these ESNs is analysed individually and the power to detect an effect is related to each specific network. Given such scenarios where the same data are being collected, it would seem obvious to attempt to combine these data and analyse the pooled resource with increased power rather than separately analysing these data from each network, where each of these ESNs has a small sample size and therefore low power. These small separate ESNs may give different results, because of the difference in receiving environments and other influencing factors, and also if some locations across this broad geographical scale have not had the same exposure to the product for which the post-market effects are being assessed. The variation among sites may then hide the effect of the product that was significant at some of the sites. Therefore, combining results for different ESNs is perhaps not as straightforward as it may seem, as there may be important covariates (e.g. receiving environments (EFSA GMO Panel, 2010) and/or stressors) leading to differentiated responses across different geographical regions and different elements of variability from each constituent data supplier (see Section 4.4.1.1 of Appendix A).

More complex hierarchical models would be needed to fully investigate the advantages and disadvantages of combining data across networks. To investigate combining data from ESNs, one would need to conduct further simulation studies accounting for:

- additional levels of variation in the model hierarchy;
- different protocols in different groups;
- different lengths of time that each constituent scheme has been running;
- different numbers of ‘treated’ and ‘missed’ sites (see also Table 16 in Appendix A);
- differences in the observation error mainly owing to volunteer- or professional-based surveys.

However, this would need large-scale, complex simulation studies that are extremely difficult and time consuming. Furthermore, these analyses would probably need to be run on a case-by-case basis. Therefore, there is a potential for further simulation studies that, in collaboration with the generic approach to power estimation (see Section 4.3.3), seek to further understand the advantages in pooling data from different sources.

In the areas of bird and butterfly monitoring, combining data from national ESNs to allow population trend analysis has been successful (van Strien et al., 2001). This has been achieved by creating European-wide umbrella surveillance programmes that support their affiliated organisations in data collection and analysis and harmonising their monitoring programmes with regard to the methodology and statistical processing. Examples, such as the Pan-European Common Bird Monitoring Scheme which collated data from 27 national/regional breeding bird surveys (see 'ESP13-0110' in the inventory), are given in Section 4.

In conclusion, combining results for different ESNs is not always appropriate, as there may be important covariates (e.g. receiving environments (EFSA GMO Panel, 2010) and/or stressors) leading to differentiated responses across geographical regions and different elements of variability from each constituent data supplier. Complex hierarchical models would be needed to fully investigate the advantages and disadvantages of combining data across ESNs. As this is an important issue to improve the efficiency of using ESNs for the purpose of GS, the EFSA GMO Panel recommends further investigation of the combination of datasets from different ESNs and conducting simulation exercises on selected case-studies.

4.5. The compatibility with other datasets (including GMO registers) for analysis of trends and accessibility of data

4.5.1. Accessibility to and compatibility of datasets from different ESNs

Availability and accessibility of information/data from ESNs are addressed in Sections 3.1 and 3.2, respectively. Compatibility of datasets from different ESNs is addressed in Section 4.3.4 in terms of combining ESNs to improve their sensitivity to detect a change in an agro-ecosystem.

Data collected by different ESNs need to be put into the context of GS of GMPs. For instance, they could be corroborated with the information retrieved from questionnaires compiled by farmers (see Section 4.2.2.1 of EFSA, 2011). In practice, such an exercise would be feasible under the conditions that, for example:

- the subject monitored is the same (e.g. presence or absence of insects/birds/mammals);
- the spatial resolution (e.g. scale of monitored units, exact geographical location/compartment) of ESNs is known;
- the temporal resolution (i.e. frequency, timing) of ESNs, depending on biology and behaviour of indicator species, is known;
- the datasets from ESNs are accessible; and
- the exact sites where GMPs are cultivated are known and that this information (e.g. GMO registers) is accessible.

Site-specific factors that influence the impact of GMOs are essential in interpreting variations in observed values relative to protection goals. In the optimal situation, ESNs would monitor certain protection goals and influencing factors at the same location at the same time. The 'Observatoire de la biodiversité en milieu agricole' (ESP13-265 in Appendix B) is an example of a programme that explicitly aims to link biodiversity to agricultural practices using indicator species. Although sometimes the monitoring protocols ask for this background information, this combination was not apparent from resulting data. Only in the summary reports was the effect of some influencing factors occasionally mentioned (see Appendix A). ESNs covering the following influencing factors were identified in the inventory (see Table 13 in Appendix A): agronomic practice, plant protection, land use/management practices, other environmental conditions and other human influences. The alternative would be to analyse ESP datasets in combination with complementary datasets supplying site-specific covariates. In this area, data from professional networks (e.g. agricultural supply chains) could be of value to provide insight into the range of agricultural inputs and practices at monitoring site locations.

In the Netherlands, Hallmann et al. (2014) were able to analyse water quality monitoring data in combination with monitoring data from the Dutch Common Breeding Bird Monitoring Scheme to investigate the association between neonicotinoid concentrations in water and trends in insectivorous bird populations. However, as explained in Section 4.4, the analysis becomes more complex when this approach is used at a European level (Storkey et al., 2011).

If it is the intention to link observed changes in endpoints to modifications in influencing factors, this will require more complex models than those used in the simulation and may require case-studies in order to refine the methodology.

4.5.2. Accessibility to and compatibility with GMO registers

4.5.2.1. Accessibility to GMO registers

According to Article 31(3)(b) of Directive 2001/18/EC, Member States shall establish registers for recording the location of GMOs cultivated on their territories (hereafter referred to as 'GMO registers') for commercial purposes, i.e. for the monitoring of possible effects of such GMOs on the environment.

Current GMO registers contain variable levels of details (e.g. geo-references) with regard to location information (e.g. province, municipality, field/parcel number) across Member States. The information recorded in the GMO registers is made available to the public subject to the data protection legislation that the Member State has in place.

However, the GMO registers constitute a valuable tool to establish a possible causal link between an effect observed by an ESN and the cultivation of GMPs in the context of GS (see Section 4.3.1).

4.5.2.2. Compatibility with GMO registers

The centralised reporting points, as suggested by the EFSA GMO Panel (EFSA 2011), would benefit from incorporating the information of the GMO registers, including the precise location references of the GMP production units, in order to be correlated with observations/data collected by ESNs. This would allow applicants and Member States to determine whether the (adverse) effect observed can be associated with the cultivation of the GMP. Correlation would be facilitated by a standardised data recording system (e.g. geo-referenced data stored in a harmonised format according to INSPIRE Directive 2007/2/EC[43]) (see Section 3.2).

Compatibility of spatial information (i.e. GMP production sites and sampling locations by ESNs) would facilitate:

- the identification of relevant ESNs likely to be of use for GS of the GMP at stake; and where appropriate;
- the adjustment of ESNs willing to collaborate to GS of GMPs (e.g. by modifying/expanding their sampling scheme to areas where the GMP is cultivated).

4.5.2.3. Classification of monitoring sites

The purpose of GS is to detect (an unanticipated) change compared with current or normal situations, referred to as baseline(s) established prior to GMP cultivation (see Section 4.3.1). The baseline is the comparable conventional (i.e. non-GM) production system. Established ESNs and associated programmes may provide suitable baseline data that can be used to observe trends in environmental data and subsequently identify potential adverse effects that may occur. The first step is to determine if there is a plausible link between the potential adverse effect and the GMP.

In the simulation study (Section 4.4.2 of Appendix A), the power curve relationships by the 'proportion of sites treated' demonstrated that increasing this value up to a limit of 50 % could lead to significant increases in power. The term 'treated' considers both uptake of GMP cultivation and also sampling site coincidence. In an ideal ESN, a sufficient proportion of sites would occur in treated areas. This obviously would only work for that specific change and it would, a priori, not necessarily be clear what the influencing factor (treatment) would be. GS is designed to detect unanticipated adverse effects and so tailoring a survey for one specific change could be a poor use of resources. Therefore, there will inevitably be a trade-off between power for any specific change

[43] Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE). OJ L 108/1, 25.4.2007, p. 1–14.

and generality. However, it is important to recognise that when there is no bias in the uptake of a product, regionally or otherwise, one may expect a well-designed survey to achieve sufficient overlap.

In this approach, in order to detect change and identify if there is a plausible link between the potential adverse effect and the cultivated GMP, the monitoring sites or regions must be classified as either non-exposed (‘control’) or exposed (‘treated’). This would require comparing the spatial locations of the monitoring sites or regions with the known locations of GMP cultivation. However, monitoring sites are not limited to single fields and usually cover a small agricultural area. Therefore, they cannot always be classified as either non-exposed (‘control’) or exposed (‘treated’) and would rather be characterised by a level of uptake of GMPs, which makes data analysis more complex. In such cases, an alternative approach, based on historical data to establish baselines and monitoring sites over time, may be required. The GMO registers could be the source of information for GMP cultivation. Ideally, the reporting of the locations should be the same for both monitoring sites and cultivation sites in terms of scale, format and projection system. Recording and reporting locations according to the INSPIRE standard (Section 3.2) for both monitoring sites and GMO registers would ensure interoperability.

4.6. The costs associated with increasing ESN sensitivity

Section 4.3.4 stresses that increasing the sample size of any ESN activity has a positive effect on the power to detect any treatment effect. Increasing the sample size (e.g. by increasing the number of sites surveyed or sampling frequency within the monitored area) also implies extra-costs. The associated costs of increasing sample sizes depend on many different factors and are specific for each ESN and the type of data collection they carry out, which makes it very difficult to consider general implications. However, the costs associated with increasing ESN sensitivity are likely to be lower if data collection is in the hands of volunteers rather than professionals. For further details, please consult Section 4.4.1.2 of Appendix A.

The external contractor examined two specific ESNs: the Wider Countryside Butterfly Survey (WCBS) and the Countryside Survey (CS), both active in the UK. Both ESNs operate very differently and hence illustrate different possible scenarios in terms of extra-costs associated with increasing sample size:

- WCBS: In 2010, 700 sites were surveyed and sampled by trained volunteers. Over a 10-year period, a 15 % increase[44] in sample size (approximately an extra 100 sites) would imply an extra-cost estimate of € 153 000[45]. Using the generic equation to estimate the ESN sensitivity to detect a change (see Sections 4.3.2 and 4.3.3), we can estimate the increase in power if 800 sites were surveyed over 10 years against 700 sites over 10 years. In this case, the generic equation reveals that for the € 153 000 spent an estimated potential increase of 6 % in the power of the statistical analysis to detect a change could be achieved.
- CS: Every eight years, a stratified random sample of 591 sites (= 1 km^2) is surveyed by professionals with extensive quality assurance and quality control procedures in place to ensure optimum quality and efficiency of data. Within each 1 km^2, detailed data on a large variety of biophysical measurements are taken, including extensive botanical surveys, soil measurements, water quality and habitat condition. Although the extra-costs (€ 1.86 million[46] estimate) were the same in sampling 100 sites/year or 800 sites once every eight years, it would be better to sample every year (potential increases in power of up to 42 %) as opposed to surveying 800 sites once every eight years (potential increases in power of up to 11 %).

The comparison of the WCBS and CS in terms of the cost to power gained is interesting because of the differences between the two schemes in terms of volunteer and professional recording. While the use of volunteers can offer significant increases in sample size for relatively little extra-cost, it often induces further sources of variability. Furthermore, one has to recognise that there is a limit to the sample size achievable, as the pool of available volunteer surveyors is not inexhaustible. The use of professionals is more expensive, but the ability to have more control over sample location, effort, consistency and observer quality can result in higher returns in power for the same number of additional sites. Cost and sample size, along with other facets of the survey in question, should be translated into power before making any comparison. It is therefore important

[44] ± 100 sites.
[45] A conversion factor was applied to the currency reported in Appendix A.
[46] A conversion factor was applied to the currency reported in Appendix A.

when consideration is given to changing, or adding to, an existing scheme that the cost versus power relationship and the factors contributing to power are fully understood (see Section 4.4.1.2 of Appendix A).

5. New surveys and future planning

When planning new surveys or adaptations to existing programmes, the external contractor has identified key areas of study design that should be evaluated based on six dimensions of quality (see Section 3.4.2 of Appendix A). Relevance is the primary criterion. The subject of research and monitoring should fit in one or more of the protection goals and/or influencing factors. Ideally, both protection goals and influencing factors are studied at the same time and place. Similarly, the geographical scope should fit with the intended area or at least with an area that is comparable with it.

In addition, the 'generic equation' developed in the simulation study could be used to estimate the power of an existing or planned ESN to ensure sufficient power to detect change. In Appendix A, Table 16 lists the covariates for each of the network properties for count, continuous or presence/absence monitoring endpoints, and Appendix 6 provides a clear guide on how to use these models in practice to achieve estimates of power.

CONCLUSIONS

From an inventory of more than 500 current environmental organisations and almost 1 000 existing ESNs[47], the EFSA GMO Panel derived a set of assessment criteria to support the selection of ESNs suitable for GS of GMPs. In compliance with these assessment criteria, several existing ESNs have been identified as potentially suitable for GS of GMPs subject to further examination. However, the EFSA GMO Panel also identified several limitations pertaining to ESNs such as limited data accessibility, data reporting format and data connectivity with GMO registers.

The EFSA GMO Panel acknowledges that the sensitivity of the statistical analyses used by ESNs is of importance in order to detect changes. A decision tree is provided for selecting the optimal method for statistical analysis based on the study design and the datasets available from ESNs. A survey design with sufficient statistical power (> 70 %) is required to detect an effect for a particular indicator. The EFSA GMO Panel concludes that an improved statistical power might be achieved either by increasing the sample size or by combining datasets collected by different ESNs. The latter implies variable extra-costs depending on whether data collection is in the hands of volunteers or professionals.

Combining data from different ESNs might increase the power to detect changes but would require more complex data analysis, as there may be important covariates leading to differentiated responses across different geographical regions. Access to information on those covariates is essential in order to assess to what extent any adverse effect is associated with a GMP or with any other stressors.

RECOMMENDATIONS

The inventory was found to be a useful tool in the initial process of identifying ESNs suitable for GS of GMPs; it would therefore be desirable to complete, maintain and update this inventory as a resource for supporting GS.

As this is an important issue to improve the efficiency of using ESNs for the purpose of GS, the EFSA GMO Panel also recommends further investigating the combination of datasets from different ESNs and conducting simulation exercises on selected case-studies.

Monitoring the environmental impacts of GMPs should be considered as a component of the broader environmental monitoring that is required to measure impacts of land use and management on biodiversity and the environment in the EU. In order to determine which human interventions are associated with environmental impacts, the EFSA GMO Panel recommends that all relevant environmental monitoring is fully integrated, so that data on all major agricultural and land use stressors (e.g. pesticides, cropping management practices, varieties) can be collated in a harmonised way and analysed. The monitoring of GMPs would also benefit from a move towards 'open data' policies including updated and publicly accessible GMO registers. Harmonisation and synchronisation of environmental monitoring would facilitate analysis and interpretation of monitoring reports and provide a strong scientific basis for supporting land use and environmental policy.

[47] An ESN is defined as an organisation contributing to one or more environmental surveillance programme(s).

DOCUMENTATION PROVIDED TO EFSA

1. Letter from the European Commission, dated 22 May 2012, to the EFSA Executive Director asking EFSA to identify existing monitoring networks suitable to provide datasets to support post-market environmental monitoring (PMEM) of GMOs.

2. Acknowledgement letter, dated 9 July 2012, from EFSA to the European Commission.

REFERENCES

Abrahantes JC, Molenberghs G, Burzykowski T, Shkedy Z, Abad AA and Renard D, 2004. Choice of units of analysis and modeling strategies in multilevel hierarchical models. Computational Statistics & Data Analysis, 47, 537-563.

ACRE (Advisory Committee on Releases to the Environment), 2012. PMEM subgroup final report. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/239229/pmem-annexes1-7.pdf

EFSA Panel on Genetically Modified Organisms (GMO), 2010. Guidance for the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(11):1879, 111 pp. doi:10.2903/j.efsa.2010.1879

EFSA Panel on Genetically Modified Organisms (GMO), 2011. Guidance document on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants. EFSA Journal 2011;9(8): 2316, 40 pp. doi:10.2903/j.efsa.2011.2316

European Commission (EC), 2012. Towards better access to scientific information: boosting the benefits of public investments in research. COM(2012) 401 final. 12 pp. Available at: http://ec.europa.eu/research/science-society/document_library/pdf_06/era-communication-towards-better-access-to-scientific-information_en.pdf

Gathmann A, 2008. National implementation plan for MON810 monitoring in Germany – A way forward to improve General Surveillance? J. Verbr. Lebensm. 3 Supplement 2, 50.

Graef F, De Schrijver A, Murray B, 2008. GMO monitoring data coordination and harmonisation at EU level – Outcomes of the European Commission Working Group on Guidance Notes supplementing Annex VII of Directive 2001/18/EC. J. Verbr. Lebensm. 3 Supplement 2, 17-20.

Hallmann CA, Foppen RPB, van Turnhout CAM, de Kroon H and Jongejans E, 2014. Declines in insectivorous birds are associated with high neonicotinoid concentrations. Nature, 511, 341-343. doi:10.1038/nature13531

Joint Research Centre (JRC), 2014. INSPIRE Public Consultation 2014. JRC Technical Reports. Available at: http://inspire.ec.europa.eu/reports/consultations/INSPIRE_Public_Consultation_Report_final.pdf

Lang A and Bühler C, 2012. Estimation of required sampling effort for monitoring the possible effects of transgenic crops on butterflies: lessons from long-term monitoring schemes in Switzerland. Ecological Indicators, 13, 29-36.

Pannekoek J and Van Strien A, 2005. TRIM 3 Manual (TRends & Indices for Monitoring data). CBS Statistics Netherlands, 58 pp.

RIVM (Rijksinstituut voor Volksgezondheid en Milieu), 2012. General surveillance of genetically modified plants possibilities for implementation in the Netherlands. RIVM Report 601040001/2012, 59 pp. Available at: http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2012/maart/General_surveillance_of_genetically_modified_plants_Possibilities_for_implementation_in_the_Netherlands

Römbke J, Jänsch S, Roβ-Nickoll M and Toschki A, 2014. Nutzungsmöglichkeiten der Länder für das Monitoring der Umweltwirkungen gentechnisch veränderter Pflanzen. BfN-Skripten, 369, 105 S. Available at: http://www.bfn.de/fileadmin/MDB/documents/service/Skript369.pdf

Sanvido O, Romeis J ,Bigler F, 2008a. An approach for post-market monitoring of potential environmental effects of Bt-maize expressing Cry1Ab on natural enemies. Journal of Applied Entomology, 1-13.

Sanvido O, Aviron S, Romeis J, Bigler F, 2008b. Environmental post-market monitoring of Btmaize. Approaches to detect potential effects on butterflies and natural enemies. Agroscope Reckenholz-Tänikon Research Station ART. 1-12.

Smets G, Alcalde E, Andres D, Carron D, Delzenne P, Heise A, Legris G, Martinez Parrilla M, Verhaert J, Wandelt C, Ilegems M and Rüdelsheim P, 2014. The use of existing environmental networks for the post-market monitoring of GM crop cultivation in the EU. Environmental Science: Processes and Impacts, 16, 1754-1763.

Storkey J, Meyer S, Still KS and Leuschner C, 2011. The impact of agricultural intensification and land-use change on the European arable flora. Proceedings of the Royal Society Series B Biological Sciences, 279, 1421-1429.

van Strien AJ, Pannekoek J and Gibbons DW, 2001. Indexing European bird population trends using results of national monitoring schemes: a trial of a new method. Bird Study, 48, 200-213.

Wilhelm R, Sanvido O, Castanera P, Schmidt K, Schiemann J, 2009. Monitoring the commercial cultivation of Bt maize in Europe – conclusions and recommendations for future monitoring practice. Environmental Biosafety Research 8, 219-225.

Wilhelm R, Beifner L, Schmidt K, Schmidtke J, Schiemann J, 2004a. Biometrical analysis of farmers' questionnaires for the monitoring of the cultivation of genetically modified maize varieties - statistical evaluation of monitoring objectives. Nachrichtenblatt des Deutschen Pflanzenschutzdienstes 56, 206-212.

Wilhelm R, Beisner L, Schmidt K, Schmidtke J, Schiemann J, 2004b. Monitoring of the cultivation of genetically modified plants - Use of farmers' questionnaires. Nachrichtenblatt des Deutschen Pflanzenschutzdienstes 56, 184-188 with supplements.

Wilhelm R, Schiemann J, 2003. Concept for the Realisation of a GMO Monitoring in Germany. Updated English Version of "konzept zur Umsetzung eines GVO-Monitoring in Deutschland". Nachrichtenblatt des Deutschen Pflanzenschutzdienstes 55, 258-272.

APPENDICES

Appendix A. Final report by Henrys et al. (2014) – Review of statistical methods and data requirements to support post-market environmental monitoring of agro-ecosystems (see http://www.efsa.europa.eu/en/efsajournal/doc/3883ax1.pdf)

Appendix B. The inventory of existing environmental surveillance networks and associated programmes (see http://www.efsa.europa.eu/en/efsajournal/doc/3883ax2.xls)